

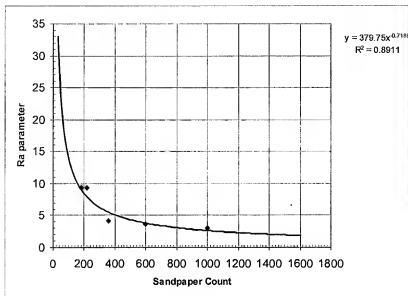
#### REMARKS

Claims 1, 3, 9, 10, 12 and 13 were pending in this application prior to the amendments herein. Claim 1 is amended herein as presented above. Support for the amendments to Claim 1 can be found at least on page 24, lines 10-17 (first and second surface of the flange insertion groove) and at least on page 24, lines 22-23 (random roughness pattern). Claims 10, 12 and 13 are cancelled without any prejudice or disclaimers, and new Claim 14 is added. Support for Claim 14 can be found at least on page 24, lines 11-14. Claims 1, 3, 9, and 14 therefore remain pending.

#### Rejections under 35 U.S.C. § 112

The Office Action rejects Claims 1, 3, 9, 10, 12 and 13 under 35 U.S.C. 112, first and second paragraph. The Office Action states that the Examiner has not been able to find a standard of roughness, which causes a problem with the claims and specification since there is no way to figure out the scope of the claims and how to determine the roughness of an element that is between No. 20 to 1500 as expressed in terms of counts of sand paper.

In section 2.3 of the article "Temporal code in the vibrissal system-Part II: Roughness surface discrimination," by Farfan et.al. that was published in the proceedings of the 16<sup>th</sup> Argentine Bioengineering Congress and the 5<sup>th</sup> Conference of Clinical Engineering, Journal of Physics: Conference Series (90), 2007, the authors show that the roughness of a surface can be correlated to the roughness of sandpaper having a certain grit size by measuring the  $R_a$  parameter of the roughened surface. The graph below shows the relation between the sandpaper count and the  $R_a$  values from the Farfan article.



As evidenced by the usage in the Farfan et al. article and the graph above, a person skilled in the art would be able to measure the  $R_a$  parameter of a surface roughened by any technique and correlate it to the average roughness of the sandpaper having a certain grit size. As a result, Applicants believe that a person skilled in the art would be able to measure the roughness of the cross section of the roughened surface of the flange and correlate it to the roughness of the grades of sand paper recited in Claim 1. As but one example of the use of sandpaper count to measure surface roughness of a material entirely unlike sandpaper, the article from the website mentioned in the Summary of Interview above refers to the roughness of deli meat and cheeses in terms of counts of sandpaper. Thus it is clear that sandpaper count can be used to measure surface roughness of a very wide variety of surfaces. As such, Applicants respectfully submit that the language disclosed in Claim 1 is sufficient to enable a person skilled in the art to make the injection apparatus commensurate in scope with the Claims 1, 3, 9 and 14.

The rejection of Claims 10, 12 and 13 is moot in view of their cancellation.

In view of the foregoing, Applicants respectfully request the Examiner to withdraw rejections of Claims 1, 3 and 9 under 35 U.S.C. § 112.

Rejections under 35 U.S.C. § 103(a)

The Office Action rejects Claims 1, 3, 9, 10, 12 and 13 as being unpatentable over U.S. Patent No. 5,407,431 by Botich et. al. in view of U.S. Publication No. 2001/0014996 A1 by Ericsson et. al. and U.S. Patent No. 4,804,368 by Skakoon et. al.

Without conceding the propriety of combining Botich with Ericsson and Skakoon, Applicants respectfully traverse this rejection on the basis that combining these references would not lead one having ordinary skill in the art to produce the presently claimed invention.

Applicants amend Claim 1 as presented above to recite:

*An injection apparatus, comprising:  
a cylinder holder that comprises a flange insertion groove having a first surface and a second surface; and  
a syringe barrel, comprising a flange adapted to be held by said flange insertion groove so as to fix the syringe barrel, said flange having a front surface and a rear surface,  
wherein said first surface of the flange insertion groove contacts the front surface of the flange and the second surface of the flange insertion groove contacts the rear surface of the flange, wherein at least one of the front surface, the rear surface of the flange, the first surface of the flange insertion groove, and the second surface of the flange insertion groove has a random roughness pattern, and wherein the cross section of the roughened surface has a roughness equivalent to that of about No. 20 to 1500 as expressed in terms of count of sand paper.*

As recognized by the Office Action, the grooves disclosed in Botich et. al. have a regular pattern. Thus, Botich fails to disclose "at least one of the front surface, and the rear surface of the flange, the first surface of the flange insertion groove, and the second surface of the flange insertion groove has a random roughness pattern" as recited by the amended Claim 1.

Moreover, the random roughness pattern recited in Claim 1 leads to unexpected results that provide strong evidence of nonobviousness as explained below.

M.P.E.P. § 716.02(a) I states: "A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness ... of the claims at issue. In re Corkill, 711 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985)." In fact, M.P.E.P. § 716.02(a) II states: "Evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut prima facie obviousness." Thus, even if the references cited did lead to a *prima facie* case of obviousness, the unexpected results discussed below would effectively rebut such a showing.

Table 1 of the specification as filed on page 27 shows the results of a pressure-resistance test conducted on an injection apparatus having a random roughness pattern on the first surface of the flange insertion groove that contacts the front surface of the flange according to the recited

claims. As evidenced by Table 1, the injection apparatus did not show any breakage of the syringe or displacement of the flange even at high injection speeds of 6 mL/sec and pressures of about 2.8-2.9 MPa.

In addition, page 23, lines 26-30 establish that roughening of a front surface or rear surface of the flange is also effective to prevent breakage.

In contrast as shown in Table 2 on page 28, all the examples of an injection apparatus without any roughened surface showed breakage and/or displacement of the flange at lesser injection speeds and pressures.

As stated in M.P.E.P. § 2145 "Rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. Rebuttal evidence may consist of a showing that the claimed compound possesses unexpected properties. Dillon, 919 F.2d at 692-93, 16 USPQ2d at 1901. A showing of unexpected results must be based on evidence, not argument or speculation."

In the present case, the ability to prevent breakage of the syringe when discharging liquid from a syringe or introducing liquid into a syringe is a significant unexpected result which is shown by evidence in Table 1 and Table 2. Botich does not suggest that an injection apparatus having a roughness pattern could increase resistance to breakage. In fact, the grooves 83 on the front surface of the flange 79 disclosed in Botich are configured to provide greater co-efficient of friction between the fingers and the thumb. See for example, column 11, lines 17-24. Moreover, as explained in the expert Declaration previously submitted, the grooves on the syringe barrel disclosed by Botich would not provide any benefit in preventing breakage of the syringe when used with a cylinder holder with flange insertion groove and if the syringe barrel disclosed by Botich or that having a similar structure were tested in the manner described in the present application, results similar to that obtained for the comparative examples having no roughened surfaces would be obtained.

Further, the other references of record do not provide any suggestion at all of anything that might be construed as suggestion that roughening could increase resistance to breakage either. Thus, it is clear that the increased resistance to breakage is a surprising and unexpected result of the presently claimed invention.

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Thus, the unexpectedness of the results obtained by the claimed invention would rebut any *prima facie* showing of obviousness, even were such a showing present.

Therefore Claims 1, 3, 9 and 14 as presented above are patentable over Botich in view of Ericsson and Skakoon both because these references do not create a *prima facie* showing of obviousness, and because the unexpected results would rebut any *prima facie* showing even were such a showing present. Accordingly, Applicants respectfully request the Examiner to withdraw rejections to Claims 1, 3, and 9 allow them to issue.

The rejection of Claim 10, 12 and 13 are moot in view of their cancellation.

Co-Pending Applications and Granted Patents of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications and granted patents of the present application's assignee.

Docket No.	Serial No.	Title	Filed
KITO2.001AUS	09/780731	SYRINGE BARREL AND CYLINDER HOLDER	02/09/2001
KITO2.001DV1	10/689367	CYLINDER HOLDER FOR A SYRINGE BARREL	10/20/2003
KITO2.001DV2	10/690685	CYLINDER HOLDER FOR A SYRINGE BARREL WITH REAR SURFACE PROJECTION	10/22/2003
KITO2.001DV3	10/691224	SYRINGE BARREL WITH GUIDE	10/22/2003
KITO2.001DV4	10/691690	SYRINGE BARREL WITH REINFORCING RIB	10/23/2003
KITO2.001DV6	12/022960	SYRINGE BARREL WITH REINFORCING RIB	01/30/2008
KITO2.001DV7	12/022906	SYRINGE BARREL WITH REINFORCING RIB	01/30/2008

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### CONCLUSION

Applicants respectfully submit that all of the pending claims are allowable. Applicants respectfully request that the Examiner withdraw the rejections and pass Claims 1, 3, 9 and 14 to issuance. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 19 Dec. 2003

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